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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,767	02/10/2004	Andrew H. Fischer	102164-0032	8715

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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

MAIL DATE	DELIVERY MODE
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05/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/775,767

Applicant(s)

FISCHER, ANDREW H.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/17/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 5/17/2004 has been considered and made of record.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the metes and bounds of the claim cannot be clearly determined. Specifically, it is not clear from the instant claim language whether or not the following elements are intended to be part of the positively claimed apparatus: “a cell sample”; “a sample port”; “a tissue cassette having attached thereto a filter”; “the reagents” and “the reagent port”. The instant claim language appears to positively recite “a cell flow pathway” defined by “an inflow tube” and “a reagent flow pathway” defined by “a plurality of reagent delivery tubes”. Note the claim merely recites that the cell flow pathway and inflow tube are intended “for delivering cell fragments from a cell sample to a sample port, the sample port being in fluid communication with a tissue cassette having attached thereto a filter”. Nothing in this claim language clearly recites that the cell sample and/or sample port and/or cassette and/or filter are part of the claimed apparatus. The same holds true for the language “for delivering the

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reagents to a reagent port in communication with the sample port". If the sample port, cassette, filter, etc. are intended to be part of the claimed apparatus, the claim language should clearly recite these elements are part of the claimed apparatus.

Claim 1 is also indefinite because the positively recited method steps only incorporate the recited filter of the device. The method steps are silent with respect to the other positively recited apparatus elements. For example, the claim recites depositing a sample of cell fragments onto the filter, however, the claim language fails to clearly set forth how the recited cell flow pathway is involved in this particular step, if at all.

Claims 2-18 are indefinite in view of their dependency on claim 1.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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6. Claims 19 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiina et al.(JP 2000-146782) in view of Kok et al.(US 4,656,047).

With respect to claim 19, the reference of Shiina et al. discloses a method for forming a cell block that includes providing a filter (1) for holding a sample of cell fragments and depositing a sample of cell fragments (See paragraph [0006] of the English language machine translation) onto the filter (1); drawing a first reagent (61) through the filter; drawing a second reagent (71) through the filter (1) and drawing a third reagent (81) through the filter (1).

Claim 19 differs by specifically reciting what each reagent does during the three different drawing steps.

The reference of Kok et al. discloses that the drawing steps required of claim 19 are conventional in the art when preparing a cell block (See column 4, lines 13-57). The reference discloses the use of a first reagent (alcohol); a second reagent (xylene); and an embedding solution (paraffin).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the reagents disclosed in the reference of Kok et al. in the system of the primary reference for the known and expected result of preparing an specimen block while providing the advantages associated with the automated system of Shiina et al.

With respect to claim 21, the system of Shiina et al. includes a reagent flow pathway having a plurality of reagent delivery tubes (6, 7, 8).

With respect to the evaporation step of claim 22, allowing evaporation of the second reagent would have been well within the purview of one having ordinary skill in the art so as to ensure that the sample is free of the second reagent prior to contact with the embedding solution.

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With respect to claim 23, it would have been obvious to one of ordinary skill in the art to remove the filter for the known and expected result of accessing the block of hardened material.

With respect to claims 24 and 25, the reference of Shiina et al. discloses the use of both positive and negative pressures for controlling the flow of reagents with respect to the filter (See elements (63,73,83) and element (6)).

7. Claims 1-6, 10-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiina et al.(JP 2000-146782) in view of Kok et al.(US 4,656,047) taken further in view of Aeikens et al.(DE 2928790).

The combination of the references of Shiina et al. and Kok et al. has been discussed above.

Claims 1 and 20 differ by reciting that the device used in the method includes a cell flow pathway. Note while the modified primary reference discloses filtering a cell sample on a filter (1) that is provided in communication with reagent delivery tubes, the reference does not disclose the use of a cell flow pathway or inflow tube for delivering cells from a cell sample to a port in communication with the filter.

The reference of Aeikens et al. discloses that it is known in the art to provide cells to a cell collection filter for tissue processing using a cell flow pathway (1) that includes a cell sample and an inflow tube for delivering the cells to a sample port (3).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the cell sample required of the primary reference using the system of the reference of

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Aeikens et al. for the known and expected result of providing an art recognized means for providing a cell sample to a filter for cell/tissue processing techniques.

With respect to claims 2-4 and 6, the reference of Kok et al. discloses the use of alcohol and xylene and paraffin.

With respect to the evaporation step of claim 5, allowing evaporation of the second reagent would have been well within the purview of one having ordinary skill in the art so as to ensure that the sample is free of the second reagent prior to contact with the embedding solution.

With respect to claims 10-13, the use of preservatives and decalcifying agents are well known in the art and their use would have been well within the purview of one having ordinary skill in the art for their known and expected advantages.

With respect to claim 14, the cells can be deposited manually as is done in the reference of Shiina et al.

With respect to claims 15-18, the reference of Shiina et al. discloses the use of both positive and negative pressures for controlling the flow of reagents with respect to the filter (See elements (63,73,83) and element (6)).

8. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiina et al.(JP 2000-146782) in view of Kok et al.(US 4,656,047) and Aeikens et al.(DE 2928790) taken further in view of McCormick (US 4,557,903).

The combination of the references of Shiina et al., Kok et al. and Aeikens et al. has been discussed above.

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Claims 7-9 differ by reciting that the method includes the additional steps of staining the cells prior to embedding the cells.

The reference of McCormick discloses that it is conventional in the art to stain cell samples prior to paraffin embedding (See column 1, lines 10-19).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to stain the cells of the modified primary reference as is conventional in the art to obtain a stained sample prior to embedding the sample. The specific stain employed would have been well within the purview of one having ordinary skill in the art.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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10. Claims 1-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,913,921 in view of Shiina et al.(JP 2000-146782) and Kok et al.(US 4,656,047).

Claims 1-18 of US Patent No. 6,913,921 encompass a device for embedding cell samples.

The claims differ by failing to recite method steps of using the recited device.

The reference of Shiina et al. discloses that it is known in the art to automate the contacting of embedding reagents with a cell sample on a filter.

The reference of Kok et al. discloses the reagents and steps employed when embedding a cell sample in a block.

In view of this teachings, it would have been obvious to one of ordinary skill in the art to employ the device of the patented claims for performing cell embedding methods as suggested by the references of Shiina et al. and Kok et al.


Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB